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August 10, 2007

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Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Art Unit 1654

Attn: Mail Stop Amendment

Re: U.S. Utility Patent Application
Application No. 10/542,704; § 371 Date: April 14, 2006
For: **Conformationally Constrained Parathyroid Hormone (PTH) Analogs With Lactam Bridges**
Inventors: GARDELLA *et al.*
Our Ref: 0609.5140000/TJS/PAC

Sir:

Transmitted herewith for appropriate action are the following documents:

1. SKGF Cover Letter;
2. Information Disclosure Statement Under 37 C.F.R. § 1.97(b);
3. Listing of the cited documents on Form PTO/SB/08A;
4. Listing of the cited documents on Form PTO/SB/08B (5 sheets);
5. A copy of the cited document FP1 on Form PTO/SB/08A;
6. A copy of thirty-seven (37) cited documents (NPL1 - NPL37) on Form PTO/SB/08B; and
7. Return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier.

In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Paul A. Calvo

Paul A. Calvo
Attorney for Applicants
Registration No. 57,913

PAC/JJY/pcd
Encls.

665898_1.DOC

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: GARDELLA *et al.*	Confirmation No.: 5389
	Art Unit: 1654
Appl. No.: 10/542,704 (U.S. Nat'l Phase of PCT/US03/02155)	Examiner: Lukton, David
§ 371 Date: April 14, 2006	Atty. Docket: 0609.5140000/TJS/PAC
For: **Conformationally Constrained Parathyroid Hormone (PTH) Analogs With Lactam Bridges**	

Information Disclosure Statement under 37 C.F.R. § 1.97(b)

Mail Stop Amendment

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying IDS Forms, PTO/SB/08A and PTO/SB/08B, are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Copies of documents **FP1** and **NPL1** to **NPL37** are submitted. However, in accordance with 37 C.F.R. § 198(a)(2), copies of U.S. patents, documents **US1** to **US5,** cited on the attached IDS Form, PTO/SB/08A, are not submitted.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicant have listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may

not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Paul A. Calvo

Paul A. Calvo
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	10/542,704 (U.S. Nat'l Phase of PCT/US03/02155)
§ 371 Date	April 14, 2006
First Named Inventor	GARDELLA, Thomas J.
Art Unit	1654
Examiner Name	Lukton, David
Attorney Docket Number	0609.5140000/TJS/PAC

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (If Known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	US1	4,675,189	06/23/1987	Kent *et al.*	
	US2	4,698,328	10/06/1987	Neer *et al.*	
	US3	4,761,406	08/02/1988	Flora *et al.*	
	US4	5,880,093	03/09/1999	Bagnoli	
	US5	6,495,662	12/17/2002	Gardella *et al.*	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	FP1	WO 01/23521	04/05/2001	The General Hospital Corporation		

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				§ 371 Date	April 14, 2006
				First Named Inventor	GARDELLA, Thomas J.
				Art Unit	1654
				Examiner Name	Lukton, David
Sheet	1	of	5	Attorney Docket Number	0609.5140000/TJS/PAC

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
	NPL1	Barden, J.A. and Kemp, B.E., "NMR Solution Structure of Human Parathyroid Hormone(1-34)," *Biochemistry 32*:7126-7132, American Chemical Society (1993)	
	NPL2	Behar, V., *et al.*, "Photoaffinity Cross-linking Identifies Differences in the Interactions of an Agonist and an Antagonist with the Parathyroid Hormone/Parathyroid Hormone-related Protein Receptor," *J. Biol. Chem. 275*:9-17, American Society for Biochemistry and Molecular Biology, Inc. (2000)	
	NPL3	Bergwitz, C., *et al.*, "Full Activation of Chimeric Receptors by Hybrids between Parathyroid Hormone and Calcitonin," *J. Biol. Chem. 271*:26469-26472, The American Society for Biochemistry and Molecular Biology, Inc. (1996)	
	NPL4	Berridge, M.J., *et al.*, "Changes in the levels of inositol phosphates after agonist-dependent hydrolysis of membrane phosphoinositides," *Biochem. J. 212*:473-482, The Biochemical Society (1983)	
	NPL5	Blackburn, C. and Kates, S.A., "Solid-Phase Synthesis of Cyclic Homodetic Peptides," *Meth. Enzymol. 289*:175-198, Academic Press (1997)	
	NPL6	Bowen, W.P. and Jerman, J.C., "Nonlinear regression using spreadsheets," *Trends Pharmacol. Sci. 16*:413-417, Elsevier Science, Ltd. (1995)	
	NPL7	Carter, P.H., *et al.*, "Studies of the N-Terminal Region of a Parathyroid Hormone-Related Peptide(1-36) Analog: Receptor Subtype-Selective Agonists, Antagonists, and Photochemical Cross-Linking Agents," *Endocrinol. 140*:4972-4981, The Endocrine Society (1999)	
	NPL8	Chen, Z., *et al.*, "Solution Structure of the Osteogenic 1-31 Fragment of the Human Parathyroid Hormone," *Biochemistry 39*:12766-12777, American Chemical Society (2000)	
	NPL9	Condon, S.M., *et al.*, "The Bioactive Conformation of Human Parathyroid Hormone. Structural Evidence for the Extended Helix Postulate," *J. Am. Chem. Soc. 122*:3007-3014, American Chemical Society (2000)	
	NPL10	Creighton, T.E., ed., "3.2. Evolutionary Divergence of Proteins," in: *Proteins: Structures and Molecular Properties*, 2nd Ed., W.H. Freeman and Co., NewYork, NY, pp. 108-114 (1993)	

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This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				Application Number	10/542,704(U.S. Nat'l Phase of PCT/US03/02155)
				§ 371 Date	April 14, 2006
				First Named Inventor	GARDELLA, Thomas J.
				Art Unit	1654
				Examiner Name	Lukton, David
Sheet	2	of	5	Attorney Docket Number	0609.5140000/TJS/PAC

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T[2]
	NPL11	Dempster, D.W., *et al.*, "Anabolic Actions of Parathyroid Hormone on Bone," *Endocrine Rev. 14*:690-709, The Endocrine Society (1993)	
	NPL12	Dempster, D.W., *et al.*, "Erratum: Anabolic Actions of Parathyroid Hormone on Bone," *Endocrine Rev. 15*:261, The Endocrine Society (1994)	
	NPL13	Fairwell, T., *et al.*, "Total Solid-Phase Synthesis, Purification, and Characterization of Human Parathyroid Hormone-(1-84)," *Biochemistry 22*:2691-2697, American Chemical Society (1983)	
	NPL14	Gronwald, W., *et al.*, "Structure of Recombinant Human Parathyroid Hormone in Solution Using Multidimensional NMR Spectroscopy," *Biol. Chem. Hoppe-Seyler 377*:175-186, Walter de Gruyter & Co. (1996)	
	NPL15	Goud, N.A., *et al.*, "Solid-Phase Synthesis and Biologic Activity of Human Parathyroid Hormone(1-84)," *J. Bone Min. Res. 6*:781-789, Mary Ann Liebert, Inc. (1991)	
	NPL16	Hoare, S.R.J., *et al.*, "Evaluating the Signal Transduction Mechanism of the Parathyroid Hormone 1 Receptor," *J. Biol. Chem. 276*:7741-7753, American Society for Biochemistry and Molecular Biology (2001)	
	NPL17	Jüppner, H., *et al.*, "A G Protein-Linked Receptor for Parathyroid Hormone and Parathyroid Hormone-Related Peptide," *Science 254:*1024-1026, American Society for the Advancement of Science (1991)	
	NPL18	Kronenberg, H.M., *et al.*, "Parathyroid Hormone: Biosynthesis, Secretion, Chemistry, and Action" in: *Handbook of Experimental Pharmacology*, Mundy, G.R., and Martin, T.J., eds., Springer-Verlag, Berlin, Germany, pp.507-567 (1993)	
	NPL19	Luck, M.D., *et al.*, "The (1-14) Fragment of Parathyroid Hormone (PTH) Activates Intact and Amino-Terminally Truncated PTH-1 Receptors," *Mol. Endocrinol. 13*:670-680, The Endocrine Society (1999)	

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Application Number	10/542,704(U.S. Nat'l Phase of PCT/US03/02155)
§ 371 Date	April 14, 2006
First Named Inventor	GARDELLA, Thomas J.
Art Unit	1654
Examiner Name	Lukton, David
Attorney Docket Number	0609.5140000/TJS/PAC

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	NPL20	Marx, U.C., *et al.*, "Structure of Human Parathyroid Hormone 1-37 in Solution," *J. Biol. Chem. 270*:15194-15202, The American Society for Biochemistry and Molecular Biology, Inc. (1995)	
	NPL21	Marx, U.C., *et al.*, "Structure Activity Relation of NH_2-Terminal Human Parathyroid Hormone Fragments," *J. Biol. Chem 273*:4308-4316, American Society for Biochemistry and Molecular Biology, Inc. (1998)	
	NPL22	Marx, U.C., *et al.*, "Solution Structure of Human Parathyroid Hormone Fragments hPTH(1-34) and hPTH (1-39) and Bovine Parathyroid Hormone Fragment bPTH(1-37)," *Biochem. Biophys. Res. Commun. 267*:213-220, Academic Press (2000)	
	NPL23	Neer, R.M., *et al.*, "Effect of Parathyroid Hormone (1-34) On Fractures and Bone Mineral Density in Postmenopausal Women with Osteoporosis," *N. Eng. J. Med. 344*:1434-1441, Massachusetts Medical Society (2001)	
	NPL24	Pellegrini, M., *et al.*, "Binding Domain of Human Parathyroid Hormone Receptor: From Conformation to Function," *Biochemistry 37*:12737-12743, American Chemical Society (1998)	
	NPL25	Robinson J.R. ed., "Methods to Achieve Controlled Drug Delivery," in: *Sustained and Controlled Release Drug Delivery Systems*, Marcel Dekker, New York,NY, pp 557-593 (1978)	
	NPL26	Shen, V., et al., "Effects of Combined and Separate Intermittent Administration of Low-Dose Human Parathyroid Hormone Fragment (1-34) and 17β-Estradiol on Bone Histomorphometery in Ovariectomized Rats with Established Osteopenia," *Calicf. Tissue Int. 50*:214-220, Springer-Verlag Inc. (1992)	
	NPL27	Shimizu, M., *et al.*, "Autoactivation of Type-1 Parathyroid Hormone Receptors Containing a Tethered Ligand," *J. Biol. Chem. 275*:19456-19460, The American Society for Biochemistry and Molecular Biology, Inc. (2000)	
	NPL28	Shimizu, M., *et al.*, "Minimization of Parathyroid Hormone," *J. Biol. Chem. 275*:21836-21843, The American Society for Biochemistry and Molecular Biology, Inc. (2000)	

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				§ 371 Date	April 14, 2006
				First Named Inventor	GARDELLA, Thomas J.
				Art Unit	1654
				Examiner Name	Lukton, David
Sheet	4	of	5	Attorney Docket Number	0609.5140000/TJS/PAC

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	NPL29	Shimizu, M., *et al.*, "Enhanced Activity in Parathyroid Hormone-(1-14) and -(1-11): Novel Peptides for Probing Ligand-Receptor Interactions," *Endocrinol. 142*:3068-3073, Endocrine Society (2001)	
	NPL30	Shimizu, N., *et al.*, "Parathyroid Hormone (PTH)-(1-14) and -(1-11) Analogs Conformationally Constrained by α-Aminoisobutyric Acid Mediate Full Agonist Responses via the Juxtamembrane Region of the PTH-1 Receptor," *J. Biol. Chem. 276*:49003-49012, The American Society for Biochemistry and Molecular Biology, Inc. (2001)	
	NPL31	Slovik, D.M., *et al.*, "Restoration of Spinal Bone in Osteoporotic Men by Treatment with Human Parathyroid Hormone (1-34) and 1,25-Dihydroxyvitamin D," *J. Bone Min. Res. 1*:377-381, Mary Ann Liebert, Inc. (1986)	
	NPL32	Takasu, H., *et al.*, "Amino Terminal Modifications of Human Parathyroid Hormone (PTH) Selectively Alter Phospholipase C Signaling via the Type 1 PTH Receptor: Implications for Design for Signal-Specific PTH Ligands," *Biochemistry 38*:13453-13460, American Chemical Society (1999)	
	NPL33	Takasu, H., *et al.*, "Dual Signaling and Ligand Selectivity of the Human PTH/PTHrP Receptor," *J. Bone Min. Res. 14*:11-20, Blackwell Science, Inc. (1999)	
	NPL34	Tregear, G.W., *et al.*, "Bovine Parathyroid Hormone: Minimum Chain Length of Synthetic Peptide Required for Biological Activity," *Endocrinol. 93*:1349-1353, The Endocrine Society (1973)	
	NPL35	Whitefield, J.F., *et al.*, "Restoration of Severely Depleted Femoral Trabecular Bone in Ovariectomized Rats by Parathyroid Hormone-(1-34)," *Calcif. Tissue Int. 56*:227-231, Springer-Verlag Inc. (1995)	
	NPL36	Whitfield, J.F., *et al.*, "Comparison of the Ability of Recombinant Human Parathyroid Hormone, rhPTH-(1-84), and hPTH-(1-31)NH_2 to Stimulate Femoral Trabecular Bone Growth in Ovariectomized Rats," *Calcif. Tissue Int. 60*:26-29, Springer-Verlag Inc. (1997)	

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				First Named Inventor	GARDELLA, Thomas J.
				Art Unit	1654
				Examiner Name	Lukton, David
Sheet	5	of	5	Attorney Docket Number	0609.5140000/TJS/PAC

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	NPL37	Wold, F., "Posttranslational Protein Modifications: Perspectives and Prospects," in *Posttranslational Covalent Modifications of Proteins*, B.C. Johnson, eds., Academic Press, Inc., New York, pp. 1-12 (1983)	

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This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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